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UNITED STATES DISTRICT COURT
SOUTHEASTERN DISTRICT OF MISSOURI

UNITED STATES OF AMERICA,)
ex rel. PAUL CAIRNS, et al.,)
)
Plaintiff,)
)
vs.)
)
D.S. MEDICAL, L.L.C., et al.,)
)
Defendants.)

Case No. 1:12CV00004 AGF

MEMORANDUM AND ORDER

This qui tam action under the False Claims Act, 31 U.S.C. §§ 3729-33 (“FCA”) is before the Court on the joint motion (ECF No. 240) of Defendants to preclude evidence of “lack of medical necessity.” For the reasons set forth below, the motion will be denied.

BACKGROUND

The operative complaint (ECF No. 26) claims that the four Defendants in the case – Dr. Sonjay Fonn, a neurosurgeon; Midwest Neurosurgeons, LLC (“Midwest Neurosurgeons”), a company formed and operated by Dr. Fonn; Deborah Seeger, Dr. Fonn’s fiancée; and D.S Medical, LLC (“DSM”), a company formed by Seeger for the distributorship of spinal implant devices – violated the FCA by submitting or causing to be submitted to the federal Medicare and Medicaid programs false claims for reimbursement for Dr. Fonn’s services in performing spinal surgeries at St. Francis Medical Center (“SFMC”) in Cape Girardeau, Missouri, between December 2008 and

March 2012, and for the purchase of implant devices used in those surgeries. The claims for reimbursement were allegedly false because they did not disclose that they were the result of alleged kickbacks that violated the federal criminal Anti-Kickback Statute (“AKS”).

The complaint alleges that Dr. Fonn would select the devices he would use during surgeries at SFMC, based, at least in part, on the fact that DSM would serve as the local distributor for the manufacturer of those devices. DSM would then be paid commissions by the manufacturers, and DSM and Seeger would in turn share those commissions with Dr. Fonn. The alleged illegal kickbacks are from Seeger and DSM to Dr. Fonn, and from spinal manufacturers to DSM and Dr. Fonn. The complaint also asserts state common law claims for payment by mistake of fact, unjust enrichment, and fraud.

In the motion under consideration, Defendants move to prohibit the introduction of evidence relating to any allegation of lack of medical necessity for the surgeries performed by Dr. Fonn and/or for the devices he used, such as statistical and anecdotal evidence of differences in medical practices between Dr. Fonn and other doctors at SFMC, and of changes in the number of devices used by Dr. Fonn after DSM came into existence. It is undisputed that the government has no medical expert who will testify on the question of lack of medical necessity or overutilization of implant devices.¹ Defendants argue that without medical expert testimony,

¹ As Defendants note, the record shows that the government attempted to procure such medical expert testimony over the years this case has been pending.

there is no way for the Government to properly argue that Dr. Fonn's number of surgeries or utilization of spinal implants was impacted by his relationship with Ms. Seeger/DSM instead of being driven by the health and medical condition of each individual patient. Unless [the Government] can put on evidence of the health condition of the patients and have an expert testify as to the necessity or lack of necessity of any particular procedure, the Government is merely attempting to allow the jury (which will not possess the proper medical background) to speculate as to why any medical procedure was performed.

ECF No. 240 at 9.

Defendants argue that, moreover, the evidence in question should be excluded under Federal Rule of Evidence 403 because its probative value is substantially outweighed by a danger of unfair prejudice to Defendants, and of confusing and misleading the jury by “suggesting corrupt or manipulative treatment of patients by Dr. Fonn.” *Id.* at 15.

In response, the government explains that its theory of the case is that the claims submitted (and caused to be submitted) by Defendants were false not because they were for medically-unnecessary services, but because the claims violated the AKS, in that they included items or services that were referred or recommended in exchange, directly or indirectly, for remuneration. Thus, the government maintains, it does not intend to prove at trial that any such items or services were medically unnecessary. But the government argues that its evidence, testimonial and otherwise, of “comparative utilization,” suggesting that Dr. Fonn used a higher number of, and more expensive, spinal devices in his surgeries than his peers, is “probative of whether he stood to profit from those practices, whether he ordered through [DSM] in exchange for that profit, and whether he acted knowingly and willfully in doing so.” ECF No. 242 at 2. According to the

government, Defendants' arguments go to the weight of that evidence, not its admissibility.²

DISCUSSION

Evidence is relevant if it “has any tendency to make a fact more or less probable than it would be without the evidence,” and if “the fact is of consequence in determining the action.” Fed. R. Evid. 401. Under Rule 403, a court “may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury” Fed. R. Evid. 403. “Rule 403 does not offer protection against evidence that is merely prejudicial in the sense of being detrimental to a party’s case. The rule protects against evidence that is unfairly prejudicial, that is, if it tends to suggest decision on an improper basis.” *United States v. Hawley*, No. C 06-4087-MWB, 2011 WL 10483390, at *6 (N.D. Iowa Oct. 13, 2011) (civil FCA case) (citation omitted). The Advisory Committee Notes to Rule 403 explain that a decision on an “improper basis” is “commonly, though not necessarily, an emotional one.” Fed. R. Evid. 403, Advisory Committee Notes.

To prevail on its claim under the FCA, the government will have to prove (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the government for payment or approval; (3) with the knowledge that the claim was false. *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005). This Court and others have held that a claim to a federal

² In light of these representations, Plaintiffs will not be permitted to argue a “lack of medical necessity.”

healthcare program for reimbursement for items or services that involved a violation of the AKS constitutes a false claim for purposes of the FCA. *See, e.g., United States ex rel. Health Dimensions Rehab., Inc. v. RehabCare Grp., Inc.*, No. 4:12CV00848 AGF, 2013 WL 4666338, at *4 (E.D. Mo. Aug. 30, 2013) (citing cases).

The AKS imposes liability on

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering or arranging for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a–7b(b)(1)(A)–(B).

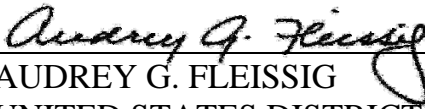
A somewhat close question is posed here. However, the Court agrees with the government that evidence of “comparative usage” of implant devices by Dr. Fonn and his peers is probative of Dr. Fonn’s intent in this case. Such evidence could support an inference that Dr. Fonn violated the AKS, and in turn, violated the FCA. While the evidence may be prejudicial, that is often the case with evidence offered by opposing counsel, and the Court does not find it is *unfairly* prejudicial. Nor is the probative value of this evidence substantially outweighed by any such prejudice. Further, any concerns regarding unfair prejudice or misleading the jury can be addressed by witness testimony, cross-examination, perhaps by a limiting instruction. *See United States v.*

Hawthorne, 235 F.3d 400, 404 (8th Cir. 2000) (finding that the relevance of evidence was not outweighed by any potential prejudice within the meaning of Rule 403 where the evidence was used for a limited purpose and the district court gave a limiting instruction).

CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that Defendants' motion in limine to preclude evidence related to the "lack of medical necessity" is **DENIED**. (ECF No. 240.)



AUDREY G. FLEISSIG
UNITED STATES DISTRICT JUDGE

Dated this 7th day of April, 2017.